



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/071,483 | 02/07/2002 | Scott L. Dax | ORT-1588 | 2756 |

27777 7590 06/12/2003
AUDLEY A. CIAMPORCERO JR.
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT PAPER NUMBER

1624

DATE MAILED: 06/12/2003

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/071,483

Applicant(s)

DAX ET AL.

Examiner

Tamthom N. Truong

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5, 8, 9, 12, and 17-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 2, 12, and 17-19 is/are rejected.
- 7) ☒ Claim(s) 3-5, 8, and 9 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

This is a divisional application of 09/626,856. The preliminary amendment of 2-7-02 has been entered. Said preliminary amendment was filed at the same time with the instant application, and thus would be considered as part of the original disclosure. However, applicant needs to refer to said amendment in the declaration. See M.P.E.P. 608.04(b).

Claims 1, 6, 7, 10, 11, and 13-16 have been cancelled. Thus, only claims 2-5, 8, 9, 12, and 17-19 remain for consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. **Indefiniteness:** Claims 2, 12, and 17-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a. Claims 2 recites variables "p" and "q" which appear to bear no relationship to the claimed formula. Clarification is solicited.
- b. Claim 12 lacks antecedent basis because the recited species lack a substituent corresponding to $-(CH_2)_m-R_2$ recited in claim 2. Note, according to claim 2, the group $(CH_2)_m-R_2$ is always there since m has a value of (at least) 1, and R_2 is hydrogen. Thus, $(CH_2)_m-R_2$ can be reduced to $-CH_3$.

c. Claims 18 and 19 are substantial duplicates because they both recite a “pharmaceutical composition” with different intended uses. However, intended uses in a composition claim do not have patentable weight.

d. Claims 17-19 are rejected as being dependent on claim 2, and carrying over its limitations.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 2, and 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by **Islam et. al.** (WO 97/19682). On pages 43, Islam et. al. disclose a compound on line 5 that is embraced by the claimed formula with the following substituents:

- i. B₁ and B₂ are both hydrogen atoms;
- ii. R₁ is halo, and R₂ represents –OH;
- iii. m = 1; Y is methylene;
- iv. L represents C₆-cycloalkylene;
- v. Z is –N-(aryl)sulfonamido.

Art Unit: 1624

Islam et. al. use said compound as an antagonist of NPY (Y^5 receptor) which can treat obesity, depression, etc. Thus, the reference reads on all limitation of the above claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 2, and 17-19 are rejected under 35 U.S.C. 102(e) as being anticipated by the following references:

e. **Dax et. al.** (US 6,201,025) : For example, see compound #28 in Table 1 on columns 33 and 34. Said compound is embraced by the claimed formula with the following substituents:

Art Unit: 1624

- vi. R_1 is H or -OMe; R_2 is aryl (or heteroaryl);
- vii. $m = 1$; $n = 1$; Y is methylene;
- viii. L represents C_{1-2} alkylene;
- ix. Z is aryl or heteroaryl;
- x. B_1 and B_2 form a six membered ring.

f. **Dax et. al.** (US 6,140,354) : For example, see compounds #52 and 57 in the Table on columns 71 and 72.

- xi. R_1 is -OMe (or halogen); R_2 is aryl;
- xii. $m = 1$; $n = 1$; Y is methylene;
- xiii. L represents C_6 cycloalkylene;
- xiv. Z is N-(aryl)sulfonamido;
- xv. B_1 and B_2 form a six membered ring.

The applied references have a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Art Unit: 1624

Claim Objections

4. Claims 3-5, 8, and 9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (9:30-5:00) & every Saturday morning (starting from 4-7-03).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Tamthom N. Truong
Examiner
Art Unit 1624

June 11, 2003